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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,420	11/26/2003	Stanley Beames Brown	0001530USQ/3049	2642

23117 7590 03/28/2007
NIXON & VANDERHYE, PC
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EXAMINER

ROYDS, LESLIE A

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,420	BROWN ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-53, 65-92, 94 and 96-100 is/are pending in the application.
- 4a) Of the above claim(s) 44-53, 65-76, 80-83, 85-88, 92, 94, 96 and 97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 77-79, 84, 89-91 and 98-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 44-53, 65-92, 94 and 96-100 are presented for examination.

Applicant's Amendment filed December 11, 2006 has been received and entered into the present application.

Claims 44-53, 65-92, 94 and 96-100 are pending. Claims 44-53, 65-76, 80-83, 85-88, 92, 94 and 96-97 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b) and claims 77-79, 84, 89-91 and 98-100 are pending and under examination. Claims 93 and 95 are cancelled and claims 98-100 are newly added and read on the elected invention.

Applicant's amendments to the claims and arguments, filed December 11, 2006, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are newly applied as a result of Applicant's amendments to the claims. They constitute the complete set of rejections presently being applied to the instant application.

Applicant is reminded that the presently claimed genus of compounds for the presently claimed methods of use are free of the prior art because the prior art at the time of the invention was such that it did not teach or fairly suggest the claimed compounds for the claimed uses.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 100 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention.

Present claim 100 is directed to a method for treating a fungal infection due to *Candida albicans*, Gram negative bacterial infection due to *E. coli* or *P. aeruginosa*, or Gram positive bacterial infection due to *S. aureus* or methicillin resistant *S. aureus* comprising the administration to a subject in need thereof, either by systemic administration or by local application to an area to be treated, a therapeutically effective amount of a compound of Formula (I) as defined in the claim, wherein said area is exposed to light to render active said compound, and further wherein said fungal infection, Gram negative bacterial infection or Gram positive bacterial infection is present in a skin disease selected from psoriasis, acne, vitiligo or eczema.

Applicant directs the Examiner to the description presented in the paragraph bridging pages 9-10 and page 10, lines 16-18 of the specification in support of this newly added claim.

While such portions of the accompanying originally filed specification have been considered, Applicant has failed to provide adequate written support for the newly claimed limitation directed to the treatment of a fungal infection due to *Candida albicans*, Gram negative bacterial infection due to *E. coli* or *P. aeruginosa*, or Gram positive bacterial infection due to *S. aureus* or methicillin resistant *S. aureus* that is specifically present in a skin disease such as psoriasis, acne, vitiligo or eczema.

Applicant states at the paragraph bridging pages 9-10 of the originally filed specification, "Examples of uses of the compounds of the present invention are as photosensitizing drugs for PDT to treat cancer and pre-cancerous conditions...tinea pedis and candida vulvovaginitis; and for use as infection preventatives such as sterilization of surgical wounds, skin graft sterilization, stem cell sterilization, graft versus host disease; to treat ophthalmological conditions such as macular degeneration, occult choroidal neovascularization (CNV), CNV due to pathological myopia...skin diseases such as psoriasis, acne, vitiligo and eczema and other dermatological conditions such as hirsutism, and sun damage, other benign conditions such as endometriosis and menorrhagia."

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Regarding Applicant's newly added limitation directed to the treatment of the claimed fungal infection, Gram negative or Gram positive bacteria infection present in a skin disease (i.e., psoriasis, acne, vitiligo or eczema), the specification and claims as originally filed fail to provide adequate written support to now narrow the treatment of psoriasis, acne, vitiligo or eczema *per se* to the treatment of a fungal infection due to *Candida albicans*, Gram negative bacterial infection due to *E. coli* or *P. aeruginosa*, or Gram positive bacterial infection due to *S. aureus* or methicillin resistant *S. aureus* that is specifically present in such a skin disease. Though Applicant discloses a use of the claimed compounds as an infection preventative for surgical wounds, skin graft, etc., it remains that the disclosure as originally filed fails to provide adequate written support for the treatment of an infection as it results in the context of the disclosed skin disease(s). Accordingly, the disclosure of the treatment of psoriasis, acne, vitiligo or eczema *per se* does not sufficiently support Applicant's new claim to the treatment of a fungal infection due to *Candida albicans*, Gram negative bacterial infection due to *E. coli* or *P. aeruginosa*, or Gram positive bacterial infection due to *S. aureus* or methicillin resistant *S. aureus* that is present in a skin disease such as psoriasis, acne, vitiligo or eczema because this represents a narrowing of the subject matter disclosed in the specification and claims as originally filed that does not have adequate written support.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of treating a fungal infection due to *Candida albicans*, Gram negative bacterial infection due to *E. coli* or *P. aeruginosa*, or Gram positive bacterial infection due to *S. aureus* or methicillin resistant *S. aureus* that is specifically present in a skin disease such as psoriasis, acne, vitiligo or eczema (claim 100).

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Accordingly, for these reasons, claim 100 is properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 77-78, 89-91 and 98-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 77, and the claims dependent therefrom, is directed to a method for treating a fungal infection due to *Candida albicans*, Gram negative bacterial infection due to *E. coli* or *P. aeruginosa*, or Gram positive bacterial infection due to *S. aureus* or methicillin resistant *S. aureus* comprising the administration to a subject in need thereof, either by systemic administration or by local application to an area to be treated, a therapeutically effective amount of a compound of Formula (I) as defined in the claim, wherein said area is exposed to light to render active said compound, and further wherein the fungal infection, Gram negative bacterial infection or Gram positive bacterial infection is treated.

Applicant's amendment to present claim 77 to now recite "or by local application to an area to be treated" does not clearly or deliberately set forth whether the area to be treated is actually one in need of treatment or whether it may be applied to any area. In other words, Applicant has failed to connect the preamble objective of treating the claimed fungal or bacterial infections specifically to the area to be treated. Accordingly, it is unclear whether the claim intends to imply that the "area to be treated" is one that is, in fact, infected or if the claimed compounds can simply be applied to an area of skin, e.g., via transdermal patch, in order to effect the treatment of the infection.

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For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 79 and 84 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting an essential step, such omission amounting to a gap between the steps. Please see MPEP § 2172.01.

Present claim 79 is directed to a method for killing, deactivating or removing any *Candida albicans*, *E.coli*, *P. aeruginosa*, *S. aureus* or methicillin resistant *S. aureus* present on a surface or in a fluid comprising contacting or applying a compound of the Formula (I) as defined in the claim to said surface or fluid and exposing said surface or fluid to which said compound has been applied or contacted to light to activate said compound and thereby kill, deactivate or remove said *Candida albicans*, *E. coli*, *P. aeruginosa*, *S. aureus* or methicillin resistant *S. aureus*. Present claim 84 is directed to substantially the same method practiced solely in a fluid, using a conjugate or composite comprising a compound of Formula (I) and a polymer.

In particular, it is noted that the preamble objective of the claim recites the “removal” of any one of the claimed microorganisms, but the claims fail to recite an active method step that would accomplish the “removal” of the microorganisms from the claimed surface or fluid. Merriam-Webster (Online, 2006) defines “remove” as “to change the location, position, station or residence of; to move by lifting, pushing aside, or taking away or off; to get rid of”. In other words, the preamble objective of “removing” implies the need for an actual physical step of taking the killed or deactivated microorganisms off or away from the surface or fluid that has been treated. In view of the fact that the claims do not recite an active step of a manner or process of actually removing the claimed microorganisms, the claims clearly omit a step that is essential to accomplishing the preamble objective.

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For these reasons, claims 79 and 84 fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and, thus, are properly rejected because they do not reasonably apprise the skilled artisan of the metes and bounds of the claim.

Conclusion

Rejection of claims 77-79, 84, 89-91 and 98-100 is proper.

Claims 44-53, 65-76, 80-83, 85-88, 92, 94 and 96-97 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

This application contains claims drawn to an invention nonelected with traverse (claims 44-53, 65-76, 80-83, 85-88, 92, 94 and 96-97) in the reply to the restriction/election requirement dated November 28, 2005. *A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

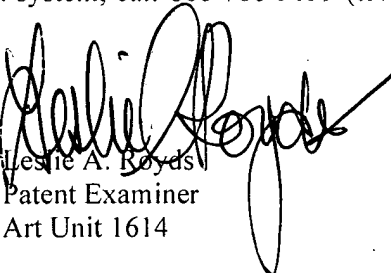
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

March 16, 2007


Leslie A. Royds
Patent Examiner
Art Unit 1614

 3/18/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER